Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Trachyspermum copticum-based traditional medicine product on clinical manifestations and Para clinical features in patients with COVID-19: A Randomized clinical trial

Protocol summary

Study aim
The effect of Trachyspermum copticum syrup on clinical presentation and respiratory infection of patients with COVID-19

Design
This is a clinical trial. In this study, there are two groups of control (who receive placebo) and the intervention group (receiving Trachyspermum copticum syrup). The number of people in each group is thirty. The study is triple blind: participants, therapeutic staff, and statistical analyst of data and drugs are blinded.

Settings and conduct
This study is carried out in Valiasr Hospital in Arak. This study is conducted by a researcher and a medical staff in a triple blind manner.

Participants/Inclusion and exclusion criteria
Patients with COVID-19, written and informed satisfaction of patients

Intervention groups
Patients with COVID-19 who have the criteria for entering the study are randomly divided into two groups then,Then for 2 weeks the patients in the intervention group will receive the Trachyspermum copticum syrup and the control group will receive placebo.

Main outcome variables
Respiratory infection

General information

Reason for update
The reason for the update is the modification of the drug manufacturer.

Acronym

IRCT registration information
IRCT registration number: **IRCT20180610040049N3**
Registration date: **2020-03-29, 1399/01/10**
Registration timing: **prospective**
Last update: **2020-04-05, 1399/01/17**
Update count: **1**

Registration date
2020-03-29, 1399/01/10

Registrant information

Name
Amirhosein Latifi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-08, 1399/01/20

Expected recruitment end date
2020-05-09, 1399/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Trachyspermum copticum-based traditional medicine product on clinical manifestations and Para clinical features in patients with COVID-19: A Randomized clinical trial

Public title
The effect of Trachyspermum copticum syrup on clinical manifestations of patients with COVID-19

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent to participate in the study The definitive diagnosis of COVID-19 Failure to attend another clinical trial simultaneously
Exclusion criteria:
Patient's willingness to use other therapies Alzheimer's patients
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The block randomization method with 4, 6 and 8 block sizes will be used to assign people to the two groups. Concealment will also be observed by using this method. In this way, each individual is assigned a unique code and is attached to drug packages that will help the blind process.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this three-blind study , patient and therapeutic personnel and data analyst do not have any type of data and medications. The drugs are encoded and placed on the patient and medical personnel.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Arak University of Medical Sciences,Basij Square
City
Arak
Province
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Postal code
3848176941
Approval date
2020-03-17, 1398/12/27
Ethics committee reference number
IR.ARAKMU.REC.1398.342

Health conditions studied

1

Description of health condition studied
Patients with Corona Virus
ICD-10 code
U07.1
ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Level of CRP in serum
Timepoint
One day before the intervention and one day after the intervention is measured
Method of measurement
Using the ELISA technique

2

Description
The rate of lung inflammation
Timepoint
One day before the intervention and one day after the intervention is measured
Method of measurement
CT SCAN

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group:" This group consumes the Trachyspermum copticum syrup. The Trachyspermum copticum plant is a member of the Umbrella family. The total extract of this plant is used.The concentration of this syrup is 10% of the aqueous extract of Trachyspermum copticum. This syrup is administered three times daily for two weeks, 5 ml each time, a total of 15 ml daily. The syrup is made by Shahid Beheshti School of Pharmacy.
Category
Treatment - Drugs

2

Description
"Control group:" This group is taking placebo. Placebo syrup have the same size and shape as the drug.The placebo syrup contains all the basic ingredients of a syrup without the addition of herbal medicine. The placebo syrup is made by Shahid Beheshti School of Pharmacy.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Valiasr Hospital.
Full name of responsible person
Seied Amirhosein Latifi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
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Position
Assistant Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable